UNITED ST[illegible] ENVIRONMENTAL PROTECTION [illegible]NCY

CASWELL FILE

DATE: JUN 26 1980

SUBJECT: Section 18 Exemption: Pirimiphos Methyl for Use on Stored Peanuts in Georgia.

TOX. Chem. No. 334BB

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PC 108102

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

Conclusion:

1. This Section 18 Exemption cannot be toxicologically supported until problems related to the neurotoxicity of this chemical are resolved.

   (NOTE: Toxicology Branch has received from the ICI Corporation a preliminary report indicating that pirimiphos methyl may cause delayed neurotoxicity. Toxicology Branch cannot on the basis of the available information determine the hazard associated with pirimiphos methyl related to neurotoxicity. The final report on this study is expected in July of 1980. See letter from J. Wagner, ICI Americas, dated May 20, 1980, EPA Acc. No. 099431).

Toxicological Considerations:

1. This Section 18 exemption requests the use of approximately 2,960 gallons of Actellic 7E (20,720 lbs. a.i., pirimiphos methyl) to treat 518,000 tons of peanuts stored in the state of Georgia. Treatment of the peanuts will be in warehouses at the time of load in at the approximate rate of 1 gallon of Actellic 7E per 175 tons of peanuts. This amount is equivalent to 20 ppm on the peanuts. A single application is scheduled to be made.

2. The formulation to be used is Actellic 7E. The inerts in this formulation have been cleared under 40 CFR 180.1001 (c). Sufficient toxicity data exists to support a "WARNING" signal word.

3. RCB (see J. Worthington memo dated February 14, 1980) has determined that residues are not expected to exceed:

   25 ppm in peanuts*
   125 ppm in peanut hulls
   50 ppm in peanut oil
   0.2 ppm in meat, milk, poultry and eggs.

   *Including metabolic products. For the purpose of this Section 18 Exemption, this figure was revised to 20 ppm, see J. Worthington memo dated May 7, 1980.

4. Requested tolerances, temporary tolerances, and EUP programs are pending with EPA. These involve peanuts and other stored grains.

5. The ADI and TMRC data are not included because action is not being favorably recommended.

6. Toxicological data considered for this Section 18 included:

   a) adequate acute toxicity data to justify a "WARNING" signal word on the label.

   b) subacute and chronic studies

90-day rat feeding	NOEL = 8 ppm (ChE and systemic)
90-day dog feeding	NOEL < 2 mg/kg/day (ChE) NOEL = 2 mg/kg/day (systemic)
Mouse oncogenesis (oral feeding)	Negative for oncogenic effect NOEL = 5 ppm (ChE)
2-year rat chronic feeding/ oncogenesis	NOEL = 10 ppm (ChE) NOEL = 300 ppm (systemic) Negative for oncogenic effect
2-year dog chronic feeding	NOEL = 0.5 mg/kg/day (ChE) NOEL = 2 mg/kg/day (systemic)
Teratology - rabbits	Negative for terata at 16 mg/kg/day
Reproduction - rats	NOEL = 100 ppm.
Neurotoxicity - hens	(Possibly neurotoxic)

7. There are no pending regulatory actions against registration of this product.

8. Pirimiphos methyl is not currently on the list of RPAR chemicals. However, chemicals demonstrating neurotoxicity are usually referred to the RPAR process.

OPP:HED:TOX: J.DOHERTY:sb 6/24/80 X73710 TS-769 Rm. 816 CM 2 #7

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Chemical:	**Pirimiphos-methyl (ANSI)**
PC Code:	***108102***
HED File Code	**14000 Risk Reviews**
Memo Date:	***06/26/80***
File ID:	**00000000**
Accession Number:	**412-03-0015**

HED Records Reference Center
09/23/2002